DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, Fl 32751

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-99-09

November 13, 1998

David E. Arjona, President
Worldtech Research Group
9140 W. Bay Harbor Drive, #3
Bay Harbor Island, Florida 33154

Dear Mr. Arjona:

This letter is in reference to your firm's marketing and distribution of "Vitamin B-17" tablets and "Apricot Seeds". Promotional material (labeling) makes therapeutic claims which cause the products to be drugs as defined in section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act). Examples of the claims for these products include:

- "Our purpose is to assist anyone in the world in obtaining the adequate amount of vitamin B-17 to treat their existing cancer";
- "...evidence that cancer is a nutritional-deficiency disease...caused by...the absence of...Vitamin B-17...the cure and prevention of cancer is simple...This concept is not approved by orthodox medicine. Yet the evidence is clear that here, at last, is the final answer to the cancer riddle.";
- "World Without Cancer, Inc., with great satisfaction, is able to present a vegetable agent whose anti-tumor action was known empirically for many years...This anti-tumor agent is Vitamin B-17 (commonly known as Amygdalin or Laetrile).";
- "Vitamin B-17 and information about it has been banned from most of the US over 15 years ago";
- "Anygdalin - Vitamin B-17": "...the ultimate cancer treatment"; and,
- "These seeds [Apricot seeds] have the highest content of B-17 on earth...The seeds may be used in combination with the Laetrile cancer therapy".

These products are "new drugs" [section 201(p) of the Act] because there is no evidence that they are generally recognized as safe and effective for their intended uses. Therefore, they may not be marketed in the United States without approved New Drug Applications [section 505(a) of the Act].

Laetrile continues to be the subject of Import Alert No. 62-01 and continues to be considered an unapproved new drug. In addition, Laetrile is not eligible for importation under the provisions of personal importation.

These drugs are also misbranded [section 502 of the Act] because the labeling fails to bear adequate directions for use. The labeling is false and misleading as it suggests that the products are safe and effective for their intended uses when, in fact, this has not been established.

This letter is not intended to be an all inclusive review of all labeling and products your firm markets. It is your responsibility to ensure that all products marketed by your firm are in compliance with the Act and its implementing regulations.

We are also aware that you are marketing the following products with objectionable claims:

- "Amygdalin (Vitamin B-17) - injectable form": claims include "Laetrile in Mexico is administered through injection...We carry the injectable form in 3 gram ampoules.";
- "Shark cartilage": claims include "not only is this a non-toxic product recommended for the treatment of cancer, but also for the treatment of inflammatory diseases such as rheumatism and osteoarthritis";
- "Preven-Ca": claims include "this product is designed to inhibit tumor growth...";
- "Kenzyme Tabs": claims include "...antineoplastic effect of pancreatic enzymes..."; and;
- "Ester-C": claims include "low levels of ascorbic acid may be associated with higher risks of cancer, heart disease, and macular degeneration...".

In addition, the "World Without Cancer" video is promoted as "perfect to give someone who has developed cancer or someone who wants to prevent cancer as it sums everything up" and the "World Without Cancer" book is promoted as "evidence that cancer is a

deficiency disease." This book and video establish the intended uses for the products "Apricot Seeds", "Vitamin B-17 tablets", and "Amygdalin (Vitamin B-17) - injectable form" in the treatment and prevention of cancer. The continued marketing of the products with the promotional materials and the objectionable claims may cause them to be violative drugs.

We request that you take prompt action to correct these violations. Failure to promptly correct violations may result in enforcement action being initiated by the Food and Drug Administration without further notice. The Federal Food, Drug, and Cosmetic Act provides for the seizure of illegal products and for injunction against the manufacturer and/or distributor of illegal products.

Please notify this office in writing within fifteen (15) working days of receipt of this letter as to the specific steps you have taken to correct the stated violations. You should also include an explanation of each step being taken to identify and make corrections to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be implemented.

Your reply should be sent to Martin E. Katz, Compliance Officer, Florida District, Food and Drug Administration, 555 Winderley Place, Ste. 200, Maitland, Florida 32751, telephone no. (407) 475-4729.

Sincerely,

Douglas D. Tolen

Douglas D. Tolen
Director, Florida District